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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,717	01/30/2004	Erik J. van der Burg	1001.2706114	5133

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EXAMINER	
BACHMAN, LINDSEY MICHELE	
ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,717	VAN DER BURG ET AL.	
	Examiner	Art Unit	
	LINDSEY BACHMAN	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 December 2010 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: Line 16 contains the word “crossection”. This is a typographical error. Appropriate correction is required.

Response to Arguments

Applicant's arguments filed 15 December 2010 have been fully considered but they are not persuasive.

Applicant states that since the implant abuts the catheter (238), the catheter can rotate the implant but the deployment line (244) cannot rotate the implant. The claim states that the deployment line is “unable to supply rotational *force* to the said device itself.” Examiner maintains that, even if the deployment line is unable to actually cause the implant to rotate (which Examiner does not necessarily agree is true), the deployment line is capable of applying a rotational *force* to the implant since the

deployment line is connected to the implant via cross-bars at the distal and proximal ends (shown, but unlabeled in Figure 33 of Applicant's drawings).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 11 were amended to recite that the deployment line is unable to supply a compressive force to the implantable device. This limitation is not disclosed in the specification. Further, according to Figure 33, which was cited in Applicant's arguments, and corresponding paragraph [0110], it appears that when the deployment line is proximally retracted, the implantable device undergoes compression initiated at distal end 190 by the deployment line when the proximal end of the implantable device is urged against the distal end of the delivery catheter to cause expansion of the implantable device. This contradicts Applicant's claim amendment.

Further, the Claim 1 recites that the deployment line supplies tension to the implantable device. The use of tension is not disclosed in the specification. Applicant does, however, refer to proximal retraction on the deployment line in paragraph [0110].

Further, Claim 1 recites that the deployment line is unable to supplying rotational force to the implantable device. The deployment line in Applicant's invention is capable of applying rotational force on the implantable device because of its connection to the implantable device. The device may not directly rotate in response to the rotation of the deployment line; however, rotational force is still applied.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. (US Patent 5,853,422) in view of Kerr (US Patent 5,941,896)

Claim 1, 2, 4, 5, 6, 7, 8: Huebsch'422 discloses a device that contains an implantable device (200, Figure 14) being movable between a reduced cross-section (Figure 14) and an enlarged cross-section (Figure 16 and 17). The implantable device has a proximal end (214) and a distal end (216) and an apex (225, 225). Huebsch'422 teaches a deployment catheter (40) and a deployment line (230; Figure 15) that is adapted to extend from the proximal to the distal end of the implantable device (see Figure 16). The proximal movement of the deployment line aids expanding the

implantable device. The deployment line is removable (via the twist lock mechanism shown in Figure 7).

Huebsch'422 does not teach the use of a sheath.

Kerr'896 teaches that it is old and well known to use an introducer catheter (28) with a delivery catheter (38) when placing a device within a vessel in the body. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art.

Claim 9, 10: Huebsch'422 teaches the use of tissue attachment elements (270) for the purpose of aiding in attaching the device to tissue (Figure 21, 22; column 7, lines 19-25).

Claim 11, 13, 14, 15, 18, 19, 20: Huebsch'422 teaches an implantable device (200; Figure 14) having a proximal end (214) and a distal end (216) and a plurality of supports (222) and a barrier (column 7, lines 43-56) movable between a reduced cross section (Figure 14) and an enlarged cross-section (Figures 16 and 17). Hubsch'422 also discloses a deployment catheter (40) and a deployment line (230; Figure 15) that is releasably attached to the implantable device ((via the twist lock mechanism shown in Figure 7) in order to move the implantable device between its collapsed and expanded positions. Implantable device (200) expands via proximal movement of the deployment line.

Regarding the limitation that the deployment line cannot apply compressive force to the device, deployment line (230) does not have an expanded portion to provide a counterforce to the implant to cause expansion of the implant like the embodiment shown in Figure 6 of Huebsch. The deployment line shown in Figure 6, for example, contains an expanded distal section 144 and an expanded proximal section 142. The expanded proximal section 142 is intended to engage with the proximal end of the implant and provide a counterforce (compression) to a tension/retraction forced applied on the distal end of the implant with expanded distal section 144 to cause the implant to expand. Since the embodiment in cited Figure 14 does not contain an expanded proximal section, the implant must deploy via a counterforce (compression) supplied by the delivery catheter with the expanded distal end section (232) is retracted. Hence, the deployment line does not apply a compressive force to the implantable device.

Huebsch'422 does not teach the use of an introducer catheter.

Kerr'896 teaches that it is old and well known to use an introducer catheter (28) with a delivery catheter (38) when placing a device within a vessel in the body. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art.

Claim 12: Huebsch'422 teaches a proximal hub (214).

Claim 16, 17: Huebsch'422 teaches the use of tissue attachment elements (270) for the purpose of aiding in attaching the device to tissue (Figure 21, 22; column 7, lines 19-25).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch'422 in view of Kerr'896, as applied to Claim 1, in view of Kotula et al (US Patent 5,846,261).

Huebsch'422 does not teach that the implantable device self expands.

Kotula'261 teaches that it is old and well known to use a shape memory alloy in an atrial septal defect closure device in order to cause the closure device to self expand (column 2, lines 50-67). It would have been obvious to one of ordinary skill in the art to modify the device of Huebsch'422 so that it too has this advantage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 4:30 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734